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PTO FACSIMILE NUMBER: (703) 872-9306

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Applicant's Name: Kimberly-Clark Worldwide, Inc.

Serial No. (Control No.): 09/998,500 **Examiner:** Kidwell

Filing Date: November 30, 2001 **Art Unit:** 3761

Application Title: BREAST PAD ASSEMBLY CONTAINING A SKIN BENEFIT INGREDIENT

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KCC 4775 (K-C 17,129)
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Beth Anne Lange Art Unit 3761
Serial No. 09/998,500
Filed November 30, 2001
Confirmation No. 6529
For BREAST PAD ASSEMBLY CONTAINING A SKIN BENEFIT INGREDIENT
Examiner Michele M. Kidwell

APPEAL BRIEF

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APPEAL BRIEF

This is an appeal from the final rejection of the claims of the above-identified application made in the Office action dated January 26, 2005. A Notice of Appeal was faxed on April 12, 2005.

I. REAL PARTY IN INTEREST

The real party in interest in connection with the present appeal is Kimberly-Clark Worldwide, Inc. of 401 N. Lake Street, Neenah, Wisconsin 54957-0349, a corporation of the state of Delaware, owner of a 100 percent interest in the pending application.

II. RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any pending appeals or interferences which may be related to, directly affect or be directly affected by, or have a bearing on, the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-71 are currently pending in the application. A copy of the pending claims appears in the Claims Appendix of this Brief.

Claims 1-71 stand rejected under 35 U.S.C. §103(a). The rejection of claims 1-71 under 35 U.S.C. §103(a) is being appealed.

IV. STATUS OF AMENDMENTS

No amendments have been filed after the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The following summary correlates claim elements to specific embodiments described in the application specification, but does not in any manner limit claim interpretation. Rather, the following summary is provided only to facilitate the Board's understanding of the subject matter of this appeal.

During breast feeding, a mother can lose a significant amount of lipids from the breast and nipple skin resulting in inflammation, redness, and potential infection to the breast and/or nipple (*see* Specification p. 2, lines 18-20). Inflammation and irritation caused by friction can be further induced to the breast and nipple by devices such as breast pads, which are used by lactating mothers to prevent breast milk leakage from contacting and seeping into and through clothing (*see* Specification p. 2, lines 5-12). This inflammation and redness may lead the mother to discontinue lactation (*see* Specification p. 1, lines 15-16). As such, a need exists in the industry for improved breast pads capable of enhancing nipple

and breast skin health while still having the ability to prevent breast milk leakage.

The present invention thus relates to breast pads incorporating a composition comprising a skin benefit ingredient for use by expectant and/or nursing mothers whose breasts have enlarged due to the presence of milk. In one embodiment, the breast pad comprises three distinct layers. The first layer, which generally faces the breast skin and nipple, is typically comprised of a wicking material for wicking moisture away from the breast to a second layer. The second layer is typically a highly absorbent layer which accepts moisture from the wicking material. This second layer is where the moisture is typically held. The third layer, which typically faces the clothes of the wearer, or the brassier, is generally comprised of a moisture resistant layer to keep the outer clothing or brassier dry (see Specification p. 5, lines 1-8).

The composition for use on the breast pad comprises a lipid comprising omega-3 fatty acids to be introduced onto the surface of a breast bad which faces the mother during use such that the omega-3 fatty acids can be transferred from the breast pad to the mother's breast skin and nipple during use to replenish skin lipids lost from the breast and nipple skin during breast feeding (Specification p. 2, lines 20-25). Lipids containing high concentrations of omega-3 fatty acids provide a significant skin health benefit to the nipple and breast skin of the woman by enhancing skin barrier properties, providing anti-inflammatory and antimicrobial activity, and by reducing friction between the breast pad and the nipple and breast skin during use of the breast pad.

Along with providing a skin health benefit to the mother by replacing lost breast and nipple skin lipids and thereby improving skin barrier functions, omega-3 fatty acids can be

ingested by the suckling infant to increase the amount of omega-3 fatty acids in the infant's diet to improve health (*see* Specification p. 2, lines 25-28). Specifically, it has been found that omega-3 fatty acids can improve the health and development of a baby's nervous and immune system (*see* Specification p. 2, lines 29-32).

In one specific embodiment, a breast pad for absorbing fluid leaking from a breast of a woman and minimizing the soiling of clothing worn by the woman comprises a front side which faces the breast and a back side which faces the clothing. The front side of the breast pad comprises from about 1.0 g/m^2 to about 30 g/m^2 of a composition for improving breast and nipple skin health. The composition comprises omega-3 fatty acids. Additionally, the composition must be suitable for ingestion by a suckling infant (*see* Specification p. 3, lines 1-6).

In additional embodiments, the composition can comprise additional ingredients for improving the health of the nipple and breast skin of the lactating mother, and the health of the infant. For example, the composition can comprise essential fatty acids (*see* Specification p. 2, lines 29-30), omega-6 fatty acids (*see* Specification p. 3, lines 11-12), flaxseed oil (*see* Specification p. 3, lines 17-19), linoleic acid, alpha linoleic acid, eicosapentenoic acid, and decosahexenoic acid (*see* Specification p. 3, lines 24-25).

VI. GROUNDS OF OBJECTIONS AND REJECTION TO BE REVIEWED ON APPEAL

The Specification stands objected as failing to provide proper antecedent basis for the claimed subject matter.

Additionally, claims 1-71 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Buckley et al. (U.S. 5,281,186) in view of Allen (U.S. 6,361,806).

VII. ARGUMENT

A. Objection to Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. Specifically, the Office asserts that the claimed language, "suitable for ingestion by a suckling infant" is not supported by the originally filed disclosure.

Applicant interprets this objection to the specification as equivalent to a rejection of the claims for lack of written description under 35 U.S.C. §112, first paragraph. Specifically, 35 U.S.C. §112, first paragraph requires the "applicant to show possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention."[1] Section 112, first paragraph further states that new or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement.[2] Applicant asserts that the amendments previously made to the claims, specifically, adding the limitation "suitable for ingestion by a suckling infant," is supported by the original disclosure, and thus, does not violate the written description requirement.

As stated in M.P.E.P. §2163.07, "[m]ere rephrasing of a

[1] M.P.E.P. §2163.
[2] *See id.*

passage does not constitute new matter. Accordingly, a rewording of a passage where the same meaning remains intact is permissible." Furthermore, the inclusion of a dictionary or art recognized definition known at the time of filing an application would not be considered new matter. Specifically, in the case of In re Anderson, 471 F.2d 1237 (CCPA 1973), the Examiner rejected a claim for containing language that had no antecedent basis in the specification and thus was new matter contrary to the requirements of 35 U.S.C. 132. In overruling the rejection, the Court of Customs and Patent Appeals, stated that "the question is not whether the word is *used* in the specification as filed but whether there is *support* in the specification for employment of the term in the claim."[3]

Applicants assert that the instant case is such a case where Applicants have simply reworded a phrase that is consistently present in the original disclosure. Direct support for the claimed language "suitable for ingestion by a suckling infant" in claims 1, 17, 35, 53, 56, 58, and 65 can be found in original claim 65, and further, in no less than 23 passages of the originally filed application.[4] Specifically, Applicants note that the instant specification discloses that "it is important that any additives introduced onto the breast pad in combination with the [omega-3 fatty acids] not be harmful to a baby if ingested by the baby during breast feeding."[5] Additionally, throughout the specification, Applicants note that the composition can be ingested by an infant during breast feeding

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[3] *In re Anderson* at 1244.

[4] *See, e.g.*, Instant application as published (U.S. Application No. 2003/0105445) at the abstract, paragraphs 5-7, 13, 15-16, 30-32, 35-37, 39-41, and 45.

[5] Instant specification at paragraph 41.

and lead to improved health for the child.[6] Furthermore, original claim 65 was directed to a method of supplementing the nutrient intake of a breast feeding infant comprising transferring the omega-3 fatty acids from the nipple and breast of the woman to the infant during the breast feeding of the infant such that the omega-3 fatty acids are ingested by the infant.

As defined in Merriam-Webster's On-line dictionary, the term "suitable" means "adapted to a use or purpose; satisfying propriety; proper; able; qualified."[7] Additionally, according to Webster's on-line dictionary, suitable means "appropriate for a condition or occasion; proper; right."[8] As such, Applicants' instant invention requires that the composition be proper or qualified for ingestion by the suckling infant.

In the Final Office Action, the Office asserts that Applicant has support for the fact that the claimed composition may be ingested by an infant, however, the fact that the composition is suitable for ingestion in the terms that the Applicant is trying to define "suitable" (i.e., safe for ingestion) has not been fully supported by the originally filed disclosure.[9] Specifically, the Office asserts that the Applicant cannot read such limitations as "not harmful" or "appropriate or meant for ingestion" into the term suitable because this interpretation is not supported by the originally filed

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[6]See, e.g., Instant specification at paragraphs 32 and 37.

[7]Website available at www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=suitable. Similar definitions can be found on www.TheFreeDictionary.com/suitable and www.hyperdictionary.com/dictionary/suitable.

[8]*See* website available at www.webster-dictionary.org/definition/suitable. In a second definition, suitable means "meant or adapted for an occasion or use."

[9]*See* "Response To Arguments," page 7 of the final Office Action.

disclosure. Applicants respectfully disagree.

When construing patent claims, there is a "heavy presumption" that the language in the claim "carries its ordinary and customary meaning."[10] As such, dictionaries and treatises may provide insight into a term's ordinary meaning thus defined. However, a claim must also be considered in the context of the intrinsic evidence, namely the claims, the specification, and the prosecution history. If there is a discernable plain and ordinary meaning of the claim language, then this meaning usually defines the scope of the claims unless the patentee has explicitly disclaimed or clearly disavowed this meaning in the specification or prosecution history.[11]

As noted above, according to Webster's on-line dictionary, the term "suitable" means "**appropriate for a condition** or occasion."[12] Applicants further agree with the Office that the term "suitable" is synonymous with "qualified" or "able". And, according to Merriam-Webster's Online dictionary, the term "qualified" means "fitted for a given purpose; having complied with the specific requirements or precedent conditions."[13] Additionally, the term "able" means "fit; adapted; suitable".[14] Furthermore, as noted above, the instant specification discloses that "it is important that any additives introduced onto the breast pad **not be harmful** to a baby if ingested by the baby

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[10]Housey Pharmaceuticals Inc. v. AstraZeneca UK Ltd., 70 USPQ2d 1641, 1644 (Fed. Cir. 2004).

[11]*See id.* Where there are several common meanings for a claim term, the patent disclosure serves to point toward the proper meaning. As such, one need not arbitrarily pick and choose from the various accepted definitions of a word to decide which meaning was intended as the work is used in a given claim. See Novartis Pharmaceuticals Corp. v. Eon Labs Manufacturing Inc., 70 USPQ2d 1438, 1441 (Fed. Cir. 2004).

[12]Website available at www.webster-dictionary.org/definition/suitable.

[13]Website available at www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=qualified.

[14]*Id.*

during breast feeding."[15] As such, there is support in the original disclosure for reading the limitations "not harmful" and "appropriate or meant for ingestion" into the claimed phrase "suitable for ingestion", as this is clear from a reading of the specification.

Additionally, at paragraph 15 of the specification, it is stated that "...fatty acids can be introduced onto the breast pad in a *suitable* composition to improve the skin health of the mother *and the health of the suckling baby.*" (Emphasis added). To be a suitable composition for improving the health of the suckling baby, the composition, by definition, must be suitable or appropriate for ingestion by the baby, otherwise it cannot improve the health of the baby. As such, the composition is suitable (i.e., appropriate or safe) for ingestion.

Based on the foregoing, Applicant asserts that the claimed language "suitable for ingestion by a suckling infant" is clearly and plainly supported by the instant specification. As such, Applicant respectfully requests reconsideration of the objection to the specification.

B. Claims 1-71 are patentable under 35 U.S.C. §103(a) over Buckley et al. (U.S. 5,281,186) in view of Allen (U.S. 6,361,806).

Claim 1 is directed to a breast pad for absorbing fluid leaking from the breast of a woman and minimizing the soiling of clothing worn by the woman. The breast pad has a front side which faces the breast and a back side which faces the clothing. The front side comprises from about 0.1 g/m^2 to about 30 g/m^2 of a composition for improving breast and nipple skin health. The composition comprises omega-3 fatty acids. The composition is

[15]Instant specification on page 17, lines 13-15.

suitable for ingestion by a suckling infant.

Buckley et al. disclose a protective breast cup arrangement comprising a plurality of breast cup members arranged to provide protection to an individual's breast region during sporting events. The cup arrangement may include a nipple pad formed from a lotion impregnated fluid absorbent sponge material. The lotion is of any type commercially available to afford protection and healing to an individual's skin or nipple.

Significantly, Buckley et al. fail to disclose a breast pad comprising from about 0.1 g/m^2 to about 30 g/m^2 of a composition for improving breast and nipple skin health comprising omega-3 fatty acids. Additionally, Buckley et al. fail to disclose a composition suitable for ingestion by a suckling infant. These are requirements of claim 1 and are important aspects of Applicant's invention. Recognizing that Buckley et al. fail to make such a disclosure, the Office cites Allen for combination with Buckley et al. in an attempt to find each and every element of Applicant's claim 1.

Allen discloses topical emollient compositions and methods that allow for topical administration of a balanced mixture of C_{18} unsaturated fatty acids that is effective to penetrate epithelial barriers and stimulate changes in fatty acid metabolism in subcutaneous adipose tissues. The compositions consist of hydrophilic:hydrophobic emulsions comprising a carrier, a vehicle, a compatible balanced fatty acid penetrant consisting of $C_{16:0}$, $C_{18:0}$ and $C_{18:1}$ fatty acid derivatives, a mixture of medicinal fatty acids, a natural anti-inflammatory compound, a natural analgesic compound, a natural estrogenic compound, and a fragrance. In one embodiment, the composition may comprise an alpha linoleic omega-3 fatty acid. The

composition is suitably applied to breast adipose tissues to improve cosmetic appearance such as an increase in size or shape, and a decrease in sagging.

In combining these references, the Office states that it would have been obvious to one of ordinary skill in the art to modify the breast pad of Buckley et al. to provide the composition taught by Allen because the composition of Allen promotes improvement of the skin. Applicants assert that such a combination is not proper, and that a careful reading of the Allen reference actually teaches away from use of their composition on a breast pad as discussed below.

As stated in M.P.E.P. §2143, in order for the Office to show a *prima facie* case of obviousness under 35 U.S.C. §103(a), the Office must meet three criteria: (1) the prior art reference(s) must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; and (3) there must be some reasonable expectation of success. Applicants assert that the Office has not, and cannot, meet the burdens of either number (1) or number (2) above, which require the Office to show each and every claim limitation and some motivation to combine the cited references. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. Applicants assert that the references, if combined do not contain all of the limitations of instant claim 1, nor is there motivation or suggestion to combine the references. Additionally, the Allen reference would actually have taught one skilled in the art away from its combination with Buckley et al.

As noted above, Buckley et al. fail to teach or suggest

each and every limitation of claim 1. Specifically, no where in the Buckley et al. reference is it taught or suggested to use a composition suitable for ingestion by a suckling infant on its protective breast pad.

The Allen reference fails to overcome the above shortcoming as Allen fails to teach or suggest a composition suitable for ingestion by a suckling infant. In considering the scope and content of a prior art reference, "[the] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention."[16] Specifically, one skilled in the art and considering the Allen reference would have realized that the compositions of Allen are not suitable for use on a breast pad because of serious health concerns to both the mother, and the nursing infant. As such, the Allen reference fails to disclose or suggest and actually teaches away from the claimed limitation of a composition suitable for ingestion by a suckling infant.

As mentioned in Applicants' specification, the omega-3 fatty acid comprising composition introduced onto the breast pad will, to some extent, be ingested by the suckling infant as the composition is transferred from the breast pad to the breast and nipple skin to facilitate repair of skin. Moreover, the instant invention provides a dual benefit in that it helps to maintain the breast and nipple skin of the mother and can also provide a dietary benefit to the suckling baby if ingested during breast feeding. The composition of Allen is strictly for topical application, as mentioned consistently throughout their disclosure, and is not designed for ingestion. There is no

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[16]W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983) (The court noted that in considering prior art references, the reader cannot "disregard disclosures in the references that diverge from and teach away from the invention at hand.") *See also* M.P.E.P. §2141.02.

mention that the composition of Allen is suitable for ingestion at all, let alone by an infant. Furthermore, as set forth in Example 1, Table A, the Allen composition may comprise sodium borate which, if ingested by an infant, can result in vomiting, diarrhea, shock and even death. As such, a close reading of the Allen reference by one skilled in the art leads to the inevitable conclusion that a chemical component used in the Allen composition for topical application is not suitable for ingestion by a suckling infant, which will happen if the composition is introduced onto a breast pad and transferred to the breast of the mother.[17]

Notwithstanding the above, even if the Buckley et al. and Allen references do suggest a composition suitable for ingestion by an infant for use on a breast pad (as noted above, Applicant's position is that the cited references clearly do not teach or suggest a composition suitable for ingestion), there is no motivation or suggestion to combine the Buckley et al. and Allen references to arrive at each and every limitation of Applicant's claim 1.

As noted above the Allen composition comprises ingredients such as sodium borate that could be harmful or even kill a nursing infant if ingested. One skilled in the art, reading the Allen reference, would not and could not be motivated to use Allen's composition on a breast pad as the composition would eventually be ingested by the nursing infant, and could kill the infant.

Additionally, the compositions of Allen comprise a natural estrogen compound. The introduction of an estrogen or estrogen producing compound into the tissue of a lactating mother can be dangerous to the health of the mother, and to the suckling

[17] Further as discussed below, the Allen composition also comprises a

infant. When considering the Allen reference as a whole, as required by the M.P.E.P., one skilled in the art would recognize that such a composition was not designed for use on a breast pad where the composition could ultimately be ingested by a nursing infant.

In addition to the composition of Allen being dangerous to both the mother and the suckling infant, one skilled in the art would not have been motivated to combine Allen with the Buckley et al. reference as the composition of Allen is not designed for treating the **surface of the nipple and skin**. As discussed in Applicants' specification, the omega-3 fatty acid-containing composition is introduced onto the breast pad such that it contacts the surface of the breast and nipple skin during use so that it can help repair skin damage on the skin surface (stratum corneum) induced by suckling by providing lipids lost from the skin surface. As disclosed throughout the instant specification, specific examples of skin damage[16] caused by breast feeding include breast and nipple infection, nipple cracking and peeling, and nipple fissures and ulcers, all which are considered damage to the surface of the breast and nipple skin.

In direct contrast, the composition of Allen is specifically designed to penetrate epithelial barriers and stimulate changes in fatty acid metabolism in subcutaneous adipose tissues; that is, the Allen composition is designed to penetrate through the stratum corneum (the lipid-containing layer of skin), through the epidermis, through the dermis, and into the underlying adipose tissue where it can stimulate changes in fatty acid metabolism. Instead of working on the

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natural estrogen, which can be dangerous to both mother and infant.

[16]Instant specification on page 4, lines 10-12.

surface of the skin similar to the composition of claim 1, the Allen composition is specifically designed to penetrate many layers of skin deep into the adipose tissue. To this end, the Allen composition comprises a penetrant, or penetration enhancing agent, effective to increase the penetration of the emulsion into the subcutaneous tissues. This is in direct contrast to an application of a composition for skin repair on the surface of the skin as the composition set forth in claim 1 seeks to do.

Because the compositions of Allen comprise a penetrant and are designed to penetrate numerous layers of skin (and therefore are not designed or intended to treat the outer layer of the skin, i.e., the stratum corneum), the compositions of Allen are not suitable for use on a breast pad to improve skin and nipple health during breast feeding. The Allen compositions simply penetrate through the outer layers and deep into the skin and thus would not be of value on the stratum corneum. One skilled in the art and reading Allen would not, and could not, have been motivated to utilize the composition on a breast pad for treating the skin by replacing lipids on the outer layer of the skin as the Allen composition is designed to penetrate deeply into the subcutaneous layers. As such, motivation to combine these references would have been lacking.

In the Examiner's "Response to Arguments" section of the final Office action, the Examiner claims that Applicants are relying on features (i.e., a composition that can be safely ingested by a suckling infant) that are not recited in the rejected claims. As stated above, the "suitable for ingestion" feature is recited in the claim and there is support for the feature in the original specification. As further stated above, a composition suitable for ingestion must be appropriate or proper for ingestion by the infant.

Furthermore, even if this feature is not recited in the claim, one skilled in the art reading the application as a whole, which, as stated above, he would be required to do, would not be motivated to combine the Buckley et al. and Allen references because the composition of the Allen reference could kill the infant, or compromise the health of the mother. This relates to the second prong the Examiner must show in making an obviousness rejection under 35 U.S.C. 103(a), that of requiring some suggestion or motivation to combine the references. This prong is distinct from the first prong requiring each and every element to be shown in the prior art references.

Additionally, the Examiner notes that the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Specifically, the Examiner finds that the intended use of ingestion of the composition by the infant to improve the health of the infant does not distinguish the instant application because "all compositions are suitable for ingestion". As noted above in the dictionary definition of suitable, all compositions are not suitable for ingestion, as a suitable composition to be ingested must be appropriate or proper for ingestion by a baby. As stated above, a composition such as the composition taught in Allen is not suitable as it could kill the infant if ingested.

Notwithstanding the above, even if all compositions are "suitable for ingestion" as suggested by the Examiner (as noted above, Applicant's position is that all compositions are clearly not suitable for ingestion as "suitable" means "appropriate or proper for a particular purpose"), one skilled in the art would not be motivated to use the composition of Allen in the breast pad of Buckley et al. to arrive at each and every element of claim 1. Specifically, one skilled in the art would not be

motivated to use a composition that could kill an infant if ingested on a breast pad. One skilled in the art would clearly recognize that a composition on a breast pad would transfer to the surface of the breast, and subsequently, could be ingested by the nursing infant. Additionally, as noted above, the Allen composition comprises a natural estrogen compound that would be introduced into the tissue of a lactating mother. This can be dangerous to the health of the lactating mother. There is simply no motivation or suggestion to combine the composition of Allen with the breast pad of Buckley et al. to arrive at Applicant's invention.

With all due respect, it appears that the Office has used hindsight analysis and reconstruction when combining the Buckley et al. reference with the Allen reference. The Federal Circuit has repeatedly cautioned against hindsight analysis and held that such practice is improper.[19] As such, even if all compositions are "suitable for ingestion," one skilled in the art, reading the Allen reference, would not and could not be motivated to use the composition of the Allen reference in the breast cup of the Buckley et al. reference as the composition could be dangerous to both the lactating mother and to the suckling infant.

Based on the foregoing, the combination of references by the Office is improper as there is no motivation or suggestion to make the combination by one skilled in the art.

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[19]Grain Processing Corp. v. American-Maize-Products, Co., 840 F.2d 902, 904 (Fed. Cir. 1988). M.P.E.P. §2142 provides that in order to reach a proper determination under 35 U.S.C. §103(a), the Examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. Knowledge of Applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences." The tendency to resort to "hindsight" based upon Applicant's disclosure is often difficult to avoid due to the very nature of the examination process.

Additionally, such a combination fails to disclose each and every element of claim 1 as there is no composition disclosed that can improve breast and nipple skin health and is suitable for ingestion by an infant. As such, claim 1 is patentable.

Claims 2-16 depend from claim 1 and are patentable for the same reasons as claim 1, as well as for the additional elements they require.

Claim 17 is similar to claim 1 with the additional requirement that the composition further comprise omega-6 fatty acids. Claim 17 is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claims 18-34 depend from claim 17 and are patentable for the same reasons as claim 17, as well as for the additional elements they require.

Claim 35 is similar to claim 1 with the additional requirement that the composition comprise essential fatty acids. Claim 35 is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claims 36-52 depend from claim 35 and are patentable for the same reasons as claim 35, as well as for the additional elements they require.

Claim 53 is similar to claim 1 and requires that the composition comprise flaxseed oil. Claim 53 is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claims 54 and 55 depend from claim 53 and are patentable for the same reasons as claim 53, as well as for the additional elements they require.

Claim 56 is similar to claim 1 wherein the composition comprises linoleic acid, alpha linoleic acid, eicosapentenoic

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However, impermissible hindsight must be avoided and the legal conclusion.

acid, and docosahexenoic acid. Claim 56 is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claim 57 depends from claim 56 and is patentable for the same reason as claim 56, as well as for the additional elements it requires.

Claim 58 is directed to a method of treating or preventing nipple tenderness and cracking comprising introducing a composition, suitable for ingestion by a suckling infant, comprising omega-3 fatty acids onto a breast pad and transferring the composition from the breast pad to the breast of the wearer. Claim 58 is similar to claim 1 and is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claims 59-64 depend from claim 58 and are patentable for the same reasons as claim 58, as well as for the additional elements they require.

Claim 65 is similar to claim 58 and is patentable for the same reasons as claim 58, as well as for the additional elements it requires.

Claims 66-71 depend from claim 65 and are patentable for the same reasons as claim 65, as well as for the additional elements they require.

VIII. Conclusion

A *prima facie* case of obviousness has not been established pursuant to 35 U.S.C. § 103, because the cited art fails to disclose, teach or suggest all the elements of claims 1-71, and because the Office has failed to show sufficient motivation for the references to be combined. For these reasons, and for those

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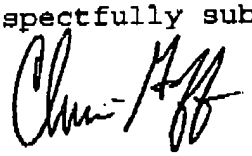
must be reached on the basis of the facts gleaned from the prior art.

more fully stated above, Appellant respectfully requests the Office's rejections be reversed and claims 1-71 be allowed.

The Commissioner is hereby authorized to charge $500 for the appeal brief and any additional fees which may be required to Deposit Account No. 19-1345.

Respectfully submitted,



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CMG/JMB

CLAIMS APPENDIX

1. (Previously Presented) A breast pad for absorbing fluid leaking from the breast of a woman and minimizing the soiling of clothing worn by the woman, said breast pad having a front side which faces the breast and a back side which faces the clothing, said front side comprising from about 0.1 g/m^2 to about 30 g/m^2 of a composition for improving breast and nipple skin health, said composition comprising omega-3 fatty acids, and wherein said composition is suitable for ingestion by a suckling infant.

2. (Original) The breast pad as set forth in claim 1 wherein the composition comprises from about 0.05% (by total weight of the composition) to about 1.5% (by total weight of the composition) omega-3 fatty acids.

3. (Original) The breast pad as set forth in claim 1 wherein the composition comprises from about 0.1% (by total weight of the composition) to about 1% (by total weight of the composition) omega-3 fatty acids.

4. (Original) The breast pad as set forth in claim 1 wherein an oil selected from the group consisting of fish oil, olive oil, canola oil, walnut oil, and flaxseed oil is introduced into the composition, said oil comprising omega-3 fatty acids.

5. (Original) The breast pad as set forth in claim 4 wherein the oil is flaxseed oil.

6. (Original) The breast pad as set forth in claim 1 further comprising an additive selected from the group consisting of a natural moisturizing factor, a humectant, vitamin C, vitamin E, aloe, and an edible botanical.

7. (Original) The breast pad as set forth in claim 1 wherein the composition has a pH of from about 3 to about 8.

8. (Original) The breast pad as set forth in claim 1 wherein the composition has a pH of from about 4 to about 6.5.

9. (Original) The breast pad as set forth in claim 1 wherein the composition further comprises from about 40% (by total weight of the composition) to about 60% (by total weight of the composition) of a solidifying agent.

10. (Original) The breast pad as set forth in claim 1 wherein the composition further comprises from about 1% (by total weight of the composition) to about 40% (by total weight of the composition) of a fatty alcohol.

11. (Original) The breast pad as set forth in claim 1 wherein the composition further comprises from about 0.1% (by total weight of the composition) to about 10% (by total weight of the composition) of an additive selected from the group consisting of sterols, sterol derivatives, and mixtures thereof.

12. (Original) The breast pad as set forth in claim 1 wherein the composition further comprises from about 0.1% (by total weight of the composition) to about 10% (by total weight of the composition) of an extracted botanical.

13. (Original) The breast pad as set forth in claim 1 wherein the composition further comprises from about 0.1% (by total weight of the composition) to about 10% (by total weight of the composition) of an emollient.

14. (Original) The breast pad as set forth in claim 1 wherein the composition further comprises from about 1% (by total weight of the composition) to about 20% (by total weight of the composition) of a viscosity enhancer.

15. (Original) The breast pad as set forth in claim 1 wherein the composition further comprises from about 0.5% (by total weight of the composition) to about 10% (by total weight of the composition) of a rheology enhancer.

16. (Original) The breast pad as set forth in claim 1 wherein the composition is in a form selected from the group consisting of an emulsion, a lotion, a cream, an ointment, a salve, a suspension, an encapsulation, and a gel.

17. (Previously Presented) A breast pad for absorbing fluid leaking from the breast of a woman and minimizing the soiling of clothing worn by the woman, said breast pad having a front side which faces the breast and a back side which faces the clothing, said front side comprising from about 0.1 g/m^2 to about 30 g/m^2 of a composition for improving breast and nipple skin health, said composition comprising omega-3 fatty acids and omega-6 fatty acids, and wherein said composition is suitable for ingestion by a suckling infant.

18. (Original) The breast pad as set forth in claim 17 wherein an oil selected from the group consisting of fish oil, olive oil, canola oil, walnut oil, and flaxseed oil is introduced into the composition, said oil comprising omega-3 fatty acids.

19. (Original) The breast pad as set forth in claim 18 wherein the oil is flaxseed oil.

20. (Previously Presented) The breast pad as set forth in claim 17 wherein an oil selected from the group consisting of corn oil, cottonseed oil, safflower oil, and sunflower oil is introduced into the composition, said oil comprising omega-6 fatty acids.

21. (Original) The breast pad as set forth in claim 17 wherein the composition comprises from about 0.05% (by total weight of the composition) to about 1.5% (by total weight of the composition) omega-3 fatty acids.

22. (Original) The breast pad as set forth in claim 17 wherein the composition comprises from about 0.1% (by total weight of the composition) to about 1% (by total weight of the composition) omega-3 fatty acids.

23. (Original) The breast pad as set forth in claim 17 wherein the weight ratio of omega-3 fatty acids to omega-6 fatty acids in the composition is from about 1:2 to about 1:4.

24. (Original) The breast pad as set forth in claim 17 further comprising an additive selected from the group consisting of a natural moisturizing factor, a humectant, vitamin C, vitamin E, aloe, and an edible botanical.

25. (Original) The breast pad as set forth in claim 17 wherein the composition has a pH of from about 3 to about 8.

26. (Original) The breast pad as set forth in claim 17 wherein the composition has a pH of from about 4 to about 6.5.

27. (Original) The breast pad as set forth in claim 17 wherein the composition further comprises from about 40% (by total weight of the composition) to about 60% (by total weight of the composition) of a solidifying agent.

28. (Original) The breast pad as set forth in claim 17 wherein the composition further comprises from about 1% (by

total weight of the composition) to about 40% (by total weight of the composition) of a fatty alcohol.

29. (Original) The breast pad as set forth in claim 17 wherein the composition further comprises from about 0.1% (by total weight of the composition) to about 10% (by total weight of the composition) of an additive selected from the group consisting of sterols, sterol derivatives, and mixtures thereof.

30. (Original) The breast pad as set forth in claim 17 wherein the composition further comprises from about 0.1% (by total weight of the composition) to about 10% (by total weight of the composition) of an extracted botanical.

31. (Original) The breast pad as set forth in claim 17 wherein the composition further comprises from about 0.1% (by total weight of the composition) to about 10% (by total weight of the composition) of an emollient.

32. (Original) The breast pad as set forth in claim 17 wherein the composition further comprises from about 1% (by total weight of the composition) to about 20% (by total weight of the composition) of a viscosity enhancer.

33. (Original) The breast pad as set forth in claim 17 wherein the composition further comprises from about 0.5% (by total weight of the composition) to about 10% (by total weight of the composition) of a rheology enhancer.

34. (Original) The breast pad as set forth in claim 17 wherein the composition is in a form selected from the group consisting of an emulsion, a lotion, a cream, an ointment, a salve, a suspension, an encapsulation, and a gel.

35. (Previously Presented) A breast pad for absorbing fluid leaking from the breast of a woman and minimizing the soiling of clothing worn by the woman, said breast pad having a front side which faces the breast and a back side which faces the clothing, said front side comprising from about 0.1 g/m^2 to about 30 g/m^2 of a composition for improving breast and nipple skin health, said composition comprising omega-3 fatty acids and essential fatty acids, and wherein said composition is suitable for ingestion by a suckling infant.

36. (Original) The breast pad as set forth in claim 35 wherein the composition comprises from about 0.05% (by total

weight of the composition) to about 1.5% (by total weight of the composition) omega-3 fatty acids.

37. (Original) The breast pad as set forth in claim 35 wherein the composition comprises from about 0.1% (by total weight of the composition) to about 1% (by total weight of the composition) omega-3 fatty acids.

38. (Original) The breast pad as set forth in claim 35 wherein the composition comprises from about 0.05% (by total weight of the composition) to about 1.5% (by total weight of the composition) essential fatty acids.

39. (Original) The breast pad as set forth in claim 35 wherein the composition comprises from about 0.1% (by total weight of the composition) to about 1% (by total weight of the composition) essential fatty acids.

40. (Previously Presented) The breast pad as set forth in claim 35 wherein the composition further comprises omega-6 fatty acids.

41. (Original) The breast pad as set forth in claim 40 wherein the weight ratio of omega-3 fatty acids to omega-6 fatty acids in the composition is from about 1:2 to about 1:4.

42. (Original) The breast pad as set forth in claim 35 further comprising an additive selected from the group consisting of a natural moisturizing factor, a humectant, vitamin C, vitamin E, aloe, and an edible botanical.

43. (Original) The breast pad as set forth in claim 35 wherein the composition has a pH of from about 3 to about 8.

44. (Original) The breast pad as set forth in claim 35 wherein the composition has a pH of from about 4 to about 6.5.

45. (Original) The breast pad as set forth in claim 35 wherein the composition further comprises from about 40% (by total weight of the composition) to about 60% (by total weight of the composition) of a solidifying agent.

46. (Original) The breast pad as set forth in claim 35 wherein the composition further comprises from about 1% (by total weight of the composition) to about 40% (by total weight of the composition) of a fatty alcohol.

47. (Original) The breast pad as set forth in claim 35 wherein the composition further comprises from about 0.1% (by total weight of the composition) to about 10% (by total weight of the composition) of an additive selected from the group consisting of sterols, sterol derivatives, and mixtures thereof.

48. (Original) The breast pad as set forth in claim 35 wherein the composition further comprises from about 0.1% (by total weight of the composition) to about 10% (by total weight of the composition) of an extracted botanical.

49. (Original) The breast pad as set forth in claim 35 wherein the composition further comprises from about 0.1% (by total weight of the composition) to about 10% (by total weight of the composition) of an emollient.

50. (Original) The breast pad as set forth in claim 35 wherein the composition further comprises from about 1% (by total weight of the composition) to about 20% (by total weight of the composition) of a viscosity enhancer.

51. (Original) The breast pad as set forth in claim 35 wherein the composition further comprises from about 0.5% (by total weight of the composition) to about 10% (by total weight of the composition) of a rheology enhancer.

52. (Original) The breast pad as set forth in claim 35 wherein the composition is in a form selected from the group consisting of an emulsion, a lotion, a cream, an ointment, a salve, a suspension, an encapsulation, and a gel.

53. (Previously Presented) A breast pad for absorbing fluid leaking from the breast of a woman and minimizing the soiling of clothing worn by the woman, said breast pad having a front side which faces the breast and a back side which faces the clothing, said front side comprising from about 0.1 g/m^2 to about 30 g/m^2 of a composition for improving breast and nipple skin health, said composition comprising from about 1% (by total weight of the composition) to about 15% (by total weight of the composition) flaxseed oil, and wherein said composition is suitable for ingestion by a suckling infant.

54. (Original) The breast pad as set forth in claim 53 wherein the composition comprises from about 1% (by total weight of the composition) to about 10% (by total weight of the composition) of flaxseed oil.

55. (Original) The breast pad as set forth in claim 53 further comprising from about 1% (by total weight of the composition) to about 15% (by total weight of the composition) of essential fatty acids.

56. (Previously Presented) A breast pad for absorbing fluid leaking from the breast of a woman and minimizing the soiling of clothing worn by the woman, said breast pad having a front side which faces the breast and a back side which faces the clothing, said front side comprising from about 0.1 g/m^2 to about 30 g/m^2 of a composition for improving breast and nipple skin health, said composition comprising linoleic acid, alpha linoleic acid, eicosapentenoic acid, and docosahexenoic acid, and wherein said composition is suitable for ingestion by a suckling infant.

57. (Original) The breast pad as set forth in claim 56 wherein the weight ratio of omega-3 fatty acids to omega-6 fatty acids in the composition is from about 1:2 to about 1:4.

58. (Previously Presented) A method of treating or preventing nipple tenderness and cracking on the breast of a breast feeding woman, the method comprising:

introducing a composition suitable for ingestion by a suckling infant onto a front side of a breast pad to be worn by the woman, said breast pad having a front side which faces the wearer and a back side which faces the clothing, said composition comprising omega-3 fatty acids and;

transferring the composition from the front side of the breast pad to the nipple and breast of the woman during wear such that the omega-3 fatty acids contact the nipple of the breast and replace skin lipids lost by the mother during the breast feeding.

59. (Original) The method as set forth in claim 58 wherein the breast pad comprises from about 0.05% (by total weight of the composition) to about 1.5% (by total weight of the composition) of omega-3 fatty acids.

60. (Original) The method as set forth in claim 58 wherein an oil selected from the group consisting of fish oil, olive oil, canola oil, walnut oil, and flaxseed oil is introduced into the composition, said oil comprising omega-3 fatty acids.

61. (Original) The method as set forth in claim 58 wherein the composition has a pH of from about 3 to about 8.

62. (Original) The method as set forth in claim 58 wherein the composition further comprises essential fatty acids.

63. (Original) The method as set forth in claim 58 wherein the composition further comprises omega-6 fatty acids.

64. (Previously Presented) The method as set forth in claim 63 wherein the weight ratio of omega-3 fatty acids to omega-6 fatty acids in the composition is from about 1:2 to about 1:4.

65. (Previously Presented) A method of supplementing the nutrient intake of a breast feeding infant, the method comprising:

introducing a composition suitable for ingestion by a suckling infant onto a front side of a breast pad to be worn by the woman breast feeding the infant, said breast pad having a front side which faces the wearer and a back side which faces the clothing, said composition comprising omega-3 fatty acids,

transferring the composition from the front side of the breast pad to the nipple and breast of the woman during wear such that the omega-3 fatty acids contacts the nipple and breast of the woman; and

transferring the omega-3 fatty acids from the nipple and breast of the woman to the infant during the breast feeding of the infant such that the omega-3 fatty acids are ingested by the infant.

66. (Original) The method as set forth in claim 65 wherein the breast pad comprises from about 0.05% (by total weight of the composition) to about 1.5% (by total weight of the composition) of omega-3 fatty acids.

67. (Original) The method as set forth in claim 65 wherein an oil selected from the group consisting of fish oil, olive oil, canola oil, walnut oil, and flaxseed oil is introduced into the composition, said oil comprising omega-3 fatty acids.

68. (Original) The method as set forth in claim 65 wherein the composition has a pH of from about 3 to about 8.

69. (Original) The method as set forth in claim 65 wherein the composition further comprises essential fatty acids.

70. (Original) The method as set forth in claim 65 wherein the composition further comprises omega-6 fatty acids.

71. (Previously Presented) The method as set forth in claim 70 wherein the weight ratio of omega-3 fatty acids to

omega-6 fatty acids in the composition is from about 1:2 to about 1:4.

KCC 4775 (K-C 17,129)
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EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.